

Report of CDC IRB “”
CDC Protocol #_____, “ ”
April 23, 2001

General Comments and IRB Actions

IRB “” reviewed your request (for new protocol approval/to continue/ to amend protocol #____ using the expedited criteria outlined in 45 CFR 46.110 (b) (1), category/ies () [Amendments only: 45 CFR 46.110 (b) (2) “minor changes to previously approved research.”] We have determined that the study (still) involves (greater than/no more than) minimal risk to subjects. Upon receipt of satisfactory responses to the following issues and concerns, and upon receipt of a clean copy/ies of the revised protocol/consent form(s)/assent form(s)/questionnaire(s), the IRB will approve (continuation of your/your amended/ your new) protocol.

Protocol Issues

Response Required, Action Required

- 1)
- 2)
- 3)

Response Required, Action Optional

- 1)
- 2)
- 3)

Of Note - No Response or Action Required

Consent Form Issues

Response Required, Action Required

- 1)
- 2)
- 3)

Response Required, Action Optional

- 1)
- 2)

Protocol # _____
Page 2 of 2

3)

Of Note - No Response or Action Required

Addenda Issues (Questionnaires, brochures, posters, etc.)

Response Required, Action Required

- 1)
- 2)
- 3)

Response Required, Action Optional

- 1)
- 2)
- 3)

Of Note - No Response or Action Required

End of Report